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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,972	07/17/2003	Ross S. Tsugita	1001.1421103	2230

28075 7590 10/15/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
10/15/2010	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/621,972
Filing Date: July 17, 2003
Appellant(s): TSUGITA, ROSS S.

Glenn Seager
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7-14-2010 appealing from the Office action mailed 10-14-2009.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application: claims 53-71 and 78-81 are rejected and pending.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 63 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 63 recites that the first catheter includes an infusion port within the proximal end region. The original disclosure discussed only an infusion port on the first catheter located at the distal end region of the first catheter. (See Figure 5)

Claims 53-58, 60-65, and 68-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028).

Gray discloses guidewire 30, filter 50 and stent (page 6, lines 15-17). Gray fails to disclose a first shaft (claim 53) or outer catheter shaft (claim 68) with a balloon coupled thereto. However, Patel teaches that a guiding catheter 11 with a balloon 25

should be used with a dilating catheter 29 in order to obtain the advantage of guiding the dilating catheter 29 within the vasculature while the balloon 25 holds the guiding catheter in place (col. 1, lines 43-52 and col. 3, lines 15-27). It would have been obvious to use a guiding catheter with a balloon with the Gray dilating catheter so that it too would have this advantage. The guiding catheter is the claimed "first shaft" (claim 53) or "outer catheter shaft" (claim 68). The guiding catheter taught by Patel has an end region extending from port 27 to the distal tip of the catheter. The portion of this end region that lies proximal to the balloon 25 is considered a proximal end region, and the portion of this end region that lies distal to the balloon 25 is considered a distal end region. There is a perfusion lumen running through this end region that allows a perfusing fluid (oxygenated blood) to pass into infusion port 27, through the perfusion lumen, and out of the distal end of the catheter and toward an inner surface of the body lumen to flush embolic debris into the filter. Since the perfusion lumen will be positioned within a body lumen, literally any direction will be toward an inner surface of the body lumen.

Regarding claim 68, there is a lumen of the guiding catheter taught by Patel running from the proximal end of the catheter shaft to the distal end of the catheter shaft. Said lumen is capable of allowing fluid to flow from the proximal end to the distal end to flush embolic debris into the filter. Although there is a port 27 through which some quantity of the fluid might escape, at least some fluid will exit through the port at the distal end of the catheter shaft.

As to claims 56-58 and 68-71, 79 and 80, Gray fails to disclose that the stent is self expanding and is retained in a collapsed configuration by a retaining sleeve. However, it is old and well known in this art to make stents self-expanding in order to obtain the advantage of enabling them to automatically expand when released by the retaining sleeve. It would have been obvious to make the Gray stent self expanding so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). Alternatively, it would have been obvious to use the first catheter as a retaining sheath for the stent since deployment systems wherein a stent is held between an inner and an outer catheter were also notoriously old and well known in the art.

Applicant has previously argued that the guiding catheter 11 and balloon 25 of Patel are not configured to stop fluid from outside the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded because the guide catheter 11 comprises port 27 which allows some quantity of blood to flow into the lumen of guide catheter 11 and to perfuse out of the tip 21. In response, Examiner first notes that the language requires only that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft from flowing distally past the distal region of the shaft. Blood that flows into port 27 is not outside of the first catheter shaft.

Claims 59, 66, 67 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (WO 99/22673) in view of Patel (4,832,028) as applied to claims 53, 56 and 68 above, and further in view of Dubrul (US 6,258,115).

Regarding claim 59, Dubrul teaches that it was known for self expanding stents to be thermally activated. (Column 9, Lines 59-60) It would have been obvious to one of ordinary skill in the art to use a thermally activated self-expanding stent since such stents were well known alternatives to the balloon expandable stents discussed in Gray and this substitution would not have produced unexpected results.

Regarding claims 66, 67 and 78-81, Dubrul teaches providing a stenting and distal protection system with an aspiration device so that dislodged emboli can be aspirated from the vessel prior to un-deploying the filter and removing it. It would have been obvious to one of ordinary skill in the art to modify the system taught by Gray in view of Patel by providing an aspiration catheter in order to remove debris from the vessel and filter while the filter is disposed in the lumen as taught by Dubrul. Further, it would have been obvious to size the aspiration catheter such that it is capable of being slidably disposed in either the first/outer catheter shaft or the second/inner catheter shaft in order to allow the aspiration catheter to easily reach the procedure site.

(10) Response to Argument

Regarding the rejection of claim 63 under 35 U.S.C. 112, first paragraph, Appellant argues that that the specification provides sufficient support for an infusion port being located at a proximal end region of the first catheter shaft. Examiner notes

that the originally filed specification only mentions an infusion port in reference to element 54 in Figure 3B and element 70 in Figure 5. Infusion ports 54 and 70 both appear to be located near the distal end of catheter 30.

With regard to the obviousness rejections over Gray in view of Patel, Appellant submits that the Patel teaching of providing a port 27 that allows blood to flow into the catheter proximal of the occlusion balloon 25 would render the resulting device incapable of meeting the recited limitation requiring that the balloon and the first catheter shaft are configured to stop fluid outside of the first catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded. Appellant argues that due to the presence of this port, blood outside of the of the first catheter shaft proximal to the balloon may flow through the port, into the catheter and then distally past the distal region of the shaft when the balloon is expanded.

In response, Examiner maintains that while it may be possible for blood *within* the shaft to flow distally past the balloon, the first catheter shaft and the balloon are configured to prevent blood *outside* of the shaft from flowing distally past the balloon. The Examiner broadly interprets the term 'fluid outside of the first catheter shaft' to include only fluid that is outside the first catheter shaft at any given instant. Should a quantity of fluid flow into the shaft, it will no longer be considered to fall into the set of 'fluid outside of the first catheter shaft.' As can be seen in Figure 2 of Patel, blood that is outside the shaft 11 will not flow distally past the balloon 25 when the balloon is inflated in a lumen sized to match the balloon.

To further support the position that a catheter such as the one disclosed in Patel having an infusion port proximal to the balloon may be interpreted to be capable of preventing fluid outside of the catheter shaft from flowing distally past the balloon when the balloon is expanded, Examiner points to Appellant's claims 63 and 64 which depend from claim 53, and recite an infusion port within the proximal end region and proximal the balloon and configured to introduce blood into the perfusion lumen. Appellant's specification mentions an infusion port located proximal to a balloon only in Paragraphs 14, 30, 41 and 47 of the corresponding Pre-Grant Publication No. 2004/0006370 and in reference to the embodiments shown in Figure 3B and Figure 5. Only in Figure 5 is the infusion port located on the claimed first catheter shaft. In this embodiment, blood would be able to flow into the catheter through infusion port proximal the balloon and distally past the expanded balloon. Since claims 63 and 64 appear to refer to this embodiments in combination with the recitation that the shaft and balloon are configured to stop fluid outside of the catheter shaft proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded, the Examiner takes this as evidence that these features are not mutually exclusive.

Examiner first noted that claims 63 and 64 appear to claim the embodiment shown in Figure 5 in the action issued November 2008. Appellant did not contest this point in the response received June 2009. Examiner made this point again in the action issued October 2009, but Appellant once again failed to contest the issue in the response received December 2009. Only upon submitting a Notice of Appeal in March 2010 did Appellant take the position that the recited 'infusion port within the proximal

end region and proximal the balloon' does not refer to the elements cited in the specification as infusion ports such as infusion port 70 shown in Figure 5. At this point, Appellant took a position that the recitations in claims 63 and 64 refer instead to a port at the proximal end of the catheter shaft outside of the patient's body that allows introduction of fluid into the catheter lumen. Examiner notes that no such port is directly mentioned at any point in the specification or shown in any of the Figures. It appears that upon realizing that broadly interpreting the contested recitation in claim 53 such that the embodiment shown in Figure 5 would fall within the claim scope would weaken the argument for patentability of claim 53 over the Patel reference, Appellant has chosen to interpret the claim scope more narrowly for appeal, and in doing so, has explicitly stated that the embodiment shown in Figure 5 does not fall within the scope of claim 53. Nonetheless, Examiner maintains that this broader interpretation is reasonable, and the appearance that claims 63 and 64, depending from claim 53, were originally intended to refer to the embodiment shown in Figure 5 suggests that at one point, the Appellant agreed with this position.

Additionally, even taking Appellant's more narrow interpretation of claim 53 requiring that the catheter and balloon be capable of preventing fluid that was at some point outside the catheter shaft and proximal to the balloon from flowing distally past the distal region of the shaft when the balloon is expanded, the Patel catheter meets this limitation. Fluid is configured to flow through catheter 11, and if the pressure within catheter 11 is greater than the patient's blood pressure, fluid would flow out through port 27 and blood will not flow inward. Thus, the catheter taught in Patel is capable of

preventing flow of blood that was at some point outside the catheter shaft from flowing distally past the ballon, and meets even this more narrow interpretation of the claim language.

With regard to Appellant's submission that Patel does not disclose that the balloon 25 is occlusive, Examiner points to Col. 2, Lines 65-68, reading, "Blood is perfused through the side hole 27 and the tip 21 of the guiding catheter 11 into the main coronary 19. Blood flow is thus not restricted by the inflated balloon 25 on the guiding catheter 11." This passage clearly teaches that were the side hole 27 not present, blood flow would be occluded by the inflated balloon 25.

Appellant further argues that the motivation for the combination of Gray and Patel (to provide a guiding catheter to hold the deployment catheter steady) does not exist when looking at the Gray reference alone. Examiner fails to see the relevance of this argument and maintains that providing a guiding catheter as taught in Patel would improve the versatility and accuracy of the Gray system.

Appellant argues that the portion of the catheter 11 lying proximal to the balloon 25 cannot be considered to comprise a proximal end region since one skilled in the art would consider a proximal end region to lie near the proximal end of the catheter. Examiner sees no contradiction here. The entirety of the catheter that lies proximal to the balloon 25 is considered to comprise a proximal end region and the entirety of the catheter that lies distal to the balloon 25 is considered to comprise a distal end region. So interpreted, the proximal end region would lie near and would include the proximal end.

Regarding claims 56-58, Appellant argues that the combination of Gray and Patel fails to teach a self-expanding stent retained by either a retaining sleeve (claim 57) or the first catheter shaft (claim 58). Appellant correctly notes that Gray discloses a balloon expandable stent. In the response received in December 2009, Appellant acknowledged that self-expanding stents were a known alternative to balloon expandable stents. (See the first paragraph on Page 10 of the response.) Examiner maintains that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Gray by substituting a self-expanding stent for the balloon expandable stent since these were known alternatives and the substitution would not have produced unexpected results. Since self-expanding stents must be retained in their collapsed configurations by an outer member in order to prevent premature deployment, it would have been obvious to one of ordinary skill in the art to use either the first catheter shaft or a retaining sleeve to achieve this purpose.

Concerning the rejections of claims 59, 66, 67 and 78 over Gray in view of Patel and Dubrul, Appellant submits that Dubrul does not teach a self-expanding stent that is thermally activated but rather teaches a stent that is expanded by the action of an unspecified external agent which warms it. Examiner holds that upon being warmed, the stent of Dubrul self-expands.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Eric Blatt/

Examiner, Art Unit 3734

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/TODD E. MANAHAN/

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